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COOPERATIVE AGREEMENT NUMBER DAMD17-96-2-6019

TITLE: Cardiovascular Responsivity, Physical and Psychosocial Job Stress, and the Risk of Preterm Delivery

PRINCIPAL INVESTIGATOR: Dr. Maureen Hatch

CONTRACTING ORGANIZATION: Mount Sinai School of Medicine
New York, New York 10029

REPORT DATE: October 1997

TYPE OF REPORT: Annual

PREPARED FOR: Commander
U.S. Army Medical Research and Materiel Command
Fort Detrick, Frederick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release;
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19980114 089

DTIC QUALITY INSPECTED 3

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.

1. AGENCY USE ONLY <i>(Leave blank)</i>	2. REPORT DATE October 1997	3. REPORT TYPE AND DATES COVERED Annual (1 Oct 96 - 30 Sep 97)	
4. TITLE AND SUBTITLE Cardiovascular Responsivity, Physical and Psychosocial Job Stress, and the Risk of Preterm Delivery		5. FUNDING NUMBERS DAMD17-96-2-6019	
6. AUTHOR(S) Dr. Maureen Hatch			
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Mount Sinai School of Medicine New York, New York 10029		8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES) Commander U.S. Army Medical Research and Materiel Command Fort Detrick, Frederick, Maryland 21702-5012		10. SPONSORING/MONITORING AGENCY REPORT NUMBER	
11. SUPPLEMENTARY NOTES			
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited		12b. DISTRIBUTION CODE	
13. ABSTRACT <i>(Maximum 200)</i> Previous studies have found both African-American and military women to be at increased risk for preterm delivery. The main goal of this study is to assess the influence of blood pressure responsivity on the risk of preterm birth among women exposed to similar levels of physical and mental job stress. We are evaluating cardiac responsivity in an ethnically diverse group of active duty military women seeking prenatal care at Wilford Hall Medical Center, Lackland Air Force Base and Brooke Army Medical Center, Fort Sam Houston. As of October 10, 1997, a total of 71 pregnant women have been enrolled in our study; of these, 53 have completed a baseline questionnaire. Effects of stress factors on pregnancy outcome may be mediated through increases in maternal heart rate and blood pressure. Therefore, women with a pronounced hemodynamic response to stress could represent a group susceptible to adverse effects of exposure to job stress during pregnancy. To identify this susceptible subgroup we plan to administer a stress challenge test at 24-26 weeks of gestation; this testing is scheduled to begin in the middle of October. The possibility that race and aerobic fitness may modulate cardiovascular responsivity will be examined. The resulting information may help not only in determining work policies but also in furthering our understanding of the etiology of preterm birth.			
14. SUBJECT TERMS Defense Women's Health Research Program preterm birth, job stress, physical activity pregnant workers, cardiovascular reactivity		15. NUMBER OF PAGES 66	
16. PRICE CODE			
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT Unlimited

FOREWORD

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Maureen Hatch, PhD 10/13/97
PI - Signature Date

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INTRODUCTION

We are evaluating the hypothesis that maternal circulatory response to physical or psychological stress may lead to shortened gestation. To account for the influence of female reproductive hormones, cardiovascular responsivity is being measured for all subjects at the same point in gestation. Effects of aerobic fitness level will be explored by incorporating data from the active-duty women's most recent fitness assessments. Greater susceptibility to infection, another possible consequence of stress⁸, might also play a role in promoting preterm delivery. Stress-induced alterations in immune function may result in increased susceptibility to urogenital tract infections. There is increasing evidence that such infections raise the risk of preterm delivery³⁴. We are therefore considering the role of infection as well as stress in determining risk of preterm delivery among an ethnically diverse population of pregnant active duty women.

Preterm birth is a major cause of perinatal morbidity and mortality. While the frequency of births of low weight ($\leq 2,500$ g) infants has declined somewhat since 1970, this decline appears to have occurred primarily among full-term as opposed to preterm low birth weight infants. Furthermore, there is no evidence that the rate of births before 37 weeks of gestation has declined³. Nationally about 8-10% of all deliveries are preterm, but the rate varies considerably (e.g., from a low of 4% to as high as 15%).

Established risk factors for preterm delivery include black race, single marital status, low socioeconomic status, previous low birth weight or preterm delivery, multiple second trimester spontaneous abortions, cigarette smoking, multiple gestations, and obstetrical and medical complications such as placental abnormalities, gestational bleeding, and cervical and uterine anomalies³. Kramer has estimated, however, that only 25-30% of preterm births can be explained by known risk factors other than chronic medical conditions or pregnancy complications.

Two potentially important risk factors that have elicited considerable interest and controversy are occupational physical activity and psychosocial stress. These factors may be particularly relevant for women who have a pronounced hemodynamic response to stress.

Occupational physical activity and pregnancy outcome

Concern about possible adverse reproductive effects of employment reflects the increasing participation of pregnant women in the labor force. Although there is a substantial literature on the effect of employment-related physical activity on pregnancy outcome, no general consensus has been reached on such effects. A growing number of studies, however, suggest that prolonged standing and long working hours may pose a risk to pregnancy.

Employment per se does not appear to increase the risk of premature delivery. For example, several studies have reported that women who are employed outside the home have either no increased risk or a reduced risk of preterm delivery when compared to women who are not employed^{4,16,22,26,35}, possibly reflecting the more favorable demographic and behavioral profile of working women. An analysis of the 1980 National Natality Survey³⁷ found that pregnant women workers were more likely to be of optimal reproductive age (20-34 years old), to be more highly educated, have a higher family income, initiate prenatal care earlier, gain more weight during pregnancy, and smoke slightly less heavily. However, employed women had fewer previous births

and more unfavorable reproductive histories (more stillbirths, spontaneous abortions, and induced abortions).

Specific work conditions. During the past couple of decades several studies have examined the effect of specific occupations or working conditions on pregnancy outcome. A French study of more than 3000 workers in two hospitals²⁶ reported increased preterm birth rates among women in occupations that required prolonged standing, working on industrial machines or assembly lines, physical exertion, mentally unstimulating tasks, or a physically unpleasant work environment. This association remained after such social factors as ethnic origin and medical conditions were taken into account. However, in a subsequent survey, the investigators²⁵ were only able to confirm that two out of the five categories -- work with industrial machines and mentally unstimulating tasks--were associated with preterm birth. Similar findings have been reported in studies of nurses and non-medical staff in France³⁶ and the Netherlands^{11,21}. Specifically, preterm deliveries were more frequent among ancillary staff and for those whose work involved standing³⁶, carrying heavy loads^{11,21,36}, and heavy cleaning tasks³⁶.

Manual work and prolonged standing have been associated with both an increased risk for small-for-gestational age births as well as preterm deliveries in a large study of Guatemalan women²². U.S. and Canadian studies have also reported that prolonged standing at work is associated with preterm^{31,38} or small-for-gestational age delivery¹², while a Finnish investigation of risk factors for preterm delivery found no evidence that employment characteristics were associated with preterm birth¹⁶. A U.S. study based on the 1980 National Natality Survey³², as well as a recent study by Hatch et al¹⁷ reported that long hours of work during pregnancy were associated with fetal growth reductions. A French study indicated that women who were prescribed work leave during their pregnancy for fatigue (without a medical reason) had lower preterm rates than women who had not had such work leave²⁴, while a Canadian study reported that regular evening or night work may be a risk factor for preterm birth¹².

Military. The association between employment-related activity and pregnancy outcome has been assessed specifically for women in the military. The risk of preterm birth among U.S. Army active-duty primigravidae has been examined by Ramirez et al³³. As the authors noted, this is a unique population because of its large size and homogeneity, and because the U.S. Army military occupational specialties undergo physical demand assessments. The authors found an increased risk of preterm delivery for women employed in the highest physical activity levels. Although this relation was unchanged after adjustment for the effects of age, race, marital status, socioeconomic status, or education, the authors suggested that the results be interpreted with caution because there were missing data when maternal and infants' hospital records could not be matched. The increased risk of preterm birth among active-duty military women was, however, confirmed by Fox et al.¹³ who compared approximately 200 active-duty women to a general clinic population and a population matched for parity and race. Fox et al. also found that in addition to an elevated risk of preterm delivery, active-duty women had a two-fold increase in frequency of toxemia. There is also some indirect evidence that military women are at elevated risk. The rates of preterm delivery reported in a recent study of U.S. enlisted women -- 10.5% among whites, 13.5% among blacks -- are high relative to the rate that would be expected in a "low risk" population of healthy young women¹.

Employment-related psychosocial stress

Although many findings mentioned above implicate physical activity as deleterious for pregnancy outcome, the question has been raised whether it is employment-related psychological stress that is the important factor or whether both physical and mental stress might pose a risk. There are few published studies of psychosocial job stress, however. Researchers interested in occupational role strain have faced the dilemma of whether to use subjective assessments of job stressors, possibly contaminated by personal dispositions or traits, or objective assessments such as ratings of job titles. These latter measures, while less likely to be influenced by personal characteristics, may also be considerably less precise given variation in the stressfulness of different jobs within the same title.

Homer et al.¹⁹ assessed work-related psychosocial stress and risk of preterm, low birthweight delivery in a national sample of young pregnant women. After accounting for the physical exertion related to a job, occupational psychologic stress as measured by job title did not increase the risk of preterm birth for the sample as a whole. However, for those who did not want to remain in the labor force, work-related stress substantially increased the risk of a preterm, low birthweight delivery. Thus, the woman's motivation to work may play an important role in the impact of work-related stress on pregnancy outcome.

A group in Denmark used a measure developed by Karasek and his colleagues,²⁰ in which job strain is hypothesized to result from work involving a combination of high demands (pace, pressure) and limited latitude to make decisions about the work (low control). In this large (N=3503) prospective investigation,¹⁸ there was little evidence found that high strain jobs alone – in the absence of low latitude - were a risk factor for preterm delivery (OR=1.3 (0.7-2.2.)

More work is needed to identify factors that can make employment outside the home mentally stressful for women, and in particular pregnant women.

Stress and response to stress

Whether stress during pregnancy affects the fetus adversely is a longstanding concern. The stress process has been described as one in which "environmental demands tax or exceed the adaptive capacity of an organism, resulting in psychological and biological changes that may place persons at risk for disease"⁷. Stressors could affect outcome of pregnancy by acting directly on physiological processes - through the release of stress hormones or by altering circulatory responses or immune parameters - without the perception of stress and without the arousal of negative emotions². Alternatively, the effects of stressors may be mediated through cognitive appraisal, followed by distress if available coping resources are perceived as inadequate²³. Additional pathways by which either stressors or distress may influence pregnancy outcome are through health behaviors, including smoking, drinking alcohol, nutritional intake or the use of medical services.

Direct effects of stress on either preterm delivery or growth retardation have been thought to be mediated by the release of glucocorticoids and catecholamines (epinephrine and norepinephrine). These hormones have physical effects that may include increases in maternal heart rate and blood pressure and decreased blood flow to systems, including the uteroplacental unit, that are nonessential to the physical task. This raises the possibility that maternal cardiovascular reactivity could be an indicator of enhanced risk. Women of lower socioeconomic status and

African-American women have higher rates of preterm delivery. Among the explanations proposed to account for this are a greater susceptibility to stressors, possibly due to more marked physiological stress responses. For example, heightened stress responses resulting from the inability to attain valued goals have been implicated in the development of hypertension among African American men¹⁰. It has been proposed that a similar mechanism might account in part for the less favorable pregnancy course and outcomes of African American women⁹.

Cardiovascular reactivity. Studies of blood pressure and heart rate responses to standardized laboratory stressors (e.g., mental arithmetic tasks) show that reactivity or heightened response may be a risk factor for cardiovascular disease^{14,27}. Men exhibit greater reactivity than women²⁸, consistent with their higher risk of heart disease and suggesting a modulating role for female hormones. Such a role is supported by results from a study of pregnant women who showed a diminished blood pressure response during challenge compared to their prepregnancy levels as well as to nonpregnant controls.²⁹ Aerobic fitness has also been associated with lower heart rate reactivity³⁰ and reduced neuroendocrine responses.

BODY

Subject recruitment

Participants are prenatal patients attending Wilford Hall Medical Center, Lackland Air Force Base and Brooke Army Medical Center, Fort Sam Houston. An estimated 1600 women are seen there annually, of whom 25-30% (n=400-500) are active duty enlistees or officers rather than military dependents. Pregnant active duty women are being interviewed at entry into prenatal care and seen again between 24-26 weeks of gestation for administration of a stress challenge test to evaluate cardiovascular responsivity.

No exclusionary criteria other than multiple gestations are being imposed. If subjects have a history of hypertension, for example or a prior preterm delivery, this will be dealt with at the stage of statistical analysis. Furthermore, we are not recruiting an external control group but will make comparisons internally between women at higher and lower levels of each exposure/susceptibility measure.

The population of active-duty military women in the San Antonio, Texas area generally enters prenatal care early, between 6-12 weeks of gestation. The group is multi-ethnic: African-American, Hispanic, Asian and White. For purposes of this study, race/ethnicity is defined based on what a woman considers herself to be.

Data Collection

Data are being collected using military personnel records, medical records, psychophysiological testing and administration of structured questionnaires.

Military records. Active duty women undergo aerobic fitness testing with cycle ergometry yearly, during their birth month. A fitness assessment is recorded based on their performance, using a score of 1-6. During pregnancy women are exempt from fitness testing, and the length of time since the most recent fitness assessment will therefore vary depending on a subject's birth month. Nonetheless, the assessment from this controlled aerobic testing will be valuable as a baseline fitness measure.

The armed forces also has a system of job-related service codes. This has been used in previous studies to assign level of physical activity. We will supplement the service codes with additional data obtained through the questionnaires.

Psychophysiology Testing. At 24-26 weeks of gestation, heart rate, blood pressure and respiration will be measured during performance on computer-controlled mental arithmetic and Stroop-color word matching tasks while in the seated position. Subjects will be given general instructions about the procedures. They will rest for a 5-minute base period while blood pressure, respiration and heart rate are obtained on a minute by minute basis using a Finapres BP Monitor (Ohmeda, Atlanta, GA) and a Hewlett-Packard EKG monitor. The experimental tasks will be presented and scored on a PC compatible computer using software developed by our consultant Dr. Richard Sloan, from the Department of Behavioral Medicine at Columbia University. The order of the two tasks will be counter-balanced to insure that any differences found between the two tasks

are not due to order effects. Each task will be five minutes in length. Tasks will be separated by a five minute rest period. Post-test heart rate, blood pressure and respiration will be determined upon completion of the tasks.

Psychophysiology testing and electronic transfer of data to Columbia University have been extensively piloted. Regular testing of subjects is scheduled to begin around the middle of October, 1997.

Medical Records. A data abstraction form has been developed and reviewed by our clinical collaborator, Dr. William Barth, Chairman of the Obstetrics/Gynecology Department, Wilford Hall Medical Center. The form will be used to obtain data from the prenatal record and the labor and delivery record on: vaginal infections, pregnancy complications such as pregnancy-induced hypertension, labor length and delivery (spontaneous, induced), as well as birthweight and gestational age at delivery.

Gestational age in days will be determined whenever possible from early ultrasound examination. In a recent study of military women, about 75% of the deliveries were dated by ultrasound¹. In cases where sonography is not available, gestational age will be calculated as date of delivery minus date of the last menstrual period.

Preterm delivery: Note will be made of whether labor was induced or spontaneous. Induced deliveries will be classified as medical interventions. Spontaneous preterm deliveries will be classified as resulting from premature labor or the result of preterm premature rupture of membranes (PPROM).

Questionnaire. A structured questionnaire is being administered by trained interviewers at entry into the study, between 12-14 weeks of gestation. Certain information collected at baseline will be updated when the subject undergoes psychophysiological testing at about week 25. The following risk factors are of primary interest:

Job-related physical activity is being assessed by asking about hours worked per day and per week, hours spent sitting, hours spent standing in a sedentary posture, hours spent in light or moderate labor, or heavy or strenuous labor.

Leisure-time physical activity is being assessed based on a questionnaire developed by Dr. Leslie Bernstein⁵ that inquires about team and individual athletic activities.

Psychosocial job stress is being assessed using two approaches: (1) relevant subscales from the NIOSH job stress questionnaire, and (2) relevant scales of skill discretion necessary to apply the Karasek job strain model.

Psychological health and life stress outside of work are being assessed using the 14-item Perceived Stress Scale (PSS) developed by Sheldon Cohen⁶, the 12-item General Health Questionnaire (GHQ) developed by David Goldberg¹⁵, and the Beck Inventory Scale.

Social support system. The NIOSH instrument includes a scale measuring support from

supervisors, coworkers, friends and family. In addition, we have included items asking about intimate social support, specifically whether the subject has a work confidant and/or partner confidant.

Inflections. Data on infections during pregnancy will be collected during the follow-up interview as well as through abstraction of laboratory medical records.

Other risk factors. Questions will be included about sociodemographic and anthropometric characteristics, obstetrical, gynecological and medical history, and lifestyle factors.

Second trimester update. Subjects will be asked to update information on the major hypothesized risk factors (physical activity, occupational stress) as well as on confounding factors such as pregnancy complications and cigarette smoking. The PSS, GHQ and Beck questionnaires will be administered a second time as well.

Quality control of data collection

Immediately after completion of an interview, the interviewer (i.e., the Nurse Coordinator or her assistant) reviews the questionnaire and recontacts the participant in the event of missing data or inconsistencies. Drs. Hatch and Berkowitz will monitor interviews during visits to the study site to insure adherence to protocol, and will provide re-training as necessary. Finally, data will be entered throughout the period of data collection, and any problems identified as a result of built-in computer logic or consistency checks will be resolved by calling back study participants.

Dr. Sloan will make periodic visits to San Antonio to evaluate administration of the physiological testing protocol. In addition, computer output will be reviewed on an ongoing basis.

The quality of record abstraction will be monitored by Drs. Hatch and Berkowitz during their site visits, by re-abstracting a random sample of 5% of the records.

Data Management

For each of the 1000 women anticipated to be enrolled in the study, data will be collected by questionnaire administered at recruitment for those factors known or suspected to affect preterm delivery. Degree of physical fitness will be obtained from the most recent cycle ergonometry testing. Between approximately 24 and 26 weeks gestational age, measurement will be made of systolic and diastolic blood pressure, respiration and heart rate at baseline and during tasks known to induce psychological stress (Stroop color word test and serial subtraction). Updated information on substance use and abuse and medical and obstetrical complications will be obtained at this time as well. Finally, at delivery, gestational age will be computed to the nearest day and for preterm deliveries the etiology (spontaneous or induced) will be noted. Birthweight and any labor and neonatal complications will also be collected for descriptive purposes.

A coding system has been developed for the questionnaires and the nurse coordinator and research assistant have been trained to administer and code the questionnaires. Completed questionnaires are edited for accuracy, consistency and completeness by the nurse coordinator.

Samples of questionnaires will also be reviewed by Drs. Hatch and Berkowitz. Data will be verified using double-key entry.

The data will be entered by the research assistant in San Antonio. Dr. Lapinski has created a data-entry program using Microsoft Access that includes range and internal consistency checks. The dataset will be converted into a SAS dataset and all data analysis will be performed using SAS statistical software.

Results

In adhering to the Statement of Work, the following tasks have been accomplished during the first twelve months of our study:

- 1) Drs. Hatch and Berkowitz visited the study site at Wilford Hall Medical Center, Lackland Air Force Base; met with Dr. Barth, the study's military collaborator; interviewed and hired a Project Coordinator and research assistant; and approved the study office arrangements. Interviews were held with members of the target population to help define the range of issues to study. A second trip is being planned for the end of October.
- 2) Patient data bases and schedules of appointments were reviewed; enrollment protocol and materials were developed, including an information sheet to be distributed to all prenatal patients and an informed consent form (see Appendix 1).
- 3) The baseline and follow-up questionnaires, as well as the medical records abstract form, were designed, reviewed, revised, pilot-tested and finalized (see Appendix 2).
- 4) Data entry programs for the questionnaires were developed by Dr. Lapinski and tested.
- 5) The Project Coordinator came to New York in March to be trained by Dr. Richard Sloan in cardioresponsivity testing. The testing equipment was subsequently sent to Wilford Hall and telephone conversations were held with Dr. Sloan to insure proper functioning. The cardioresponsivity testing was then practiced on site and the resultant data were sent to Dr. Sloan for review. Dr. Sloan plans to make periodic visits to San Antonio to monitor the administration of the testing protocol and re-train as needed.
- 6) Prior to the start of patient enrollment on July 8, a patient log and non-participant questionnaire were developed to enable us to monitor study progress. The Project Coordinator sends a weekly copy of the patient log to Dr. Hatch for review.

Recruitment began on July 8. As expected, the acceptance rate for this study is high, largely because: (1) military women get release time for prenatal care visits; (2) Dr. Barth, Chairman of the Ob/Gyn Department, is a co-sponsor of the study; and (3) the study protocol does not make excessive demands on subjects; subjects may even find the stress challenge test intriguing. Therefore we are experiencing no difficulty enrolling and retaining subjects.

As of October 10, a total of 110 potentially eligible women have been contacted and asked

to participate in the study. Of these, only 2 (1.8%) refused to participate, 23 (20.9%) were excluded due to inability to remain in the San Antonio area through completion of the study, and 5 (4.5%) were excluded due to multiple gestation. An additional 9 (8.2%) women were subsequently excluded due to spontaneous pregnancy termination. Thus, a total of 71 pregnant women have been enrolled in our study to date; of these, 53 have completed a baseline questionnaire and the completeness of reporting is 100%.

Of the 53 women who have completed a baseline questionnaire to date, the ethnic breakdown is as follows: 28 (52.8%) White, 15 (28.3%) Black, 2 (3.8%) Asian, 6 (11.3%) Hispanic, and 2 (3.8%) Native American. 39 of the women are in the Air Force, vs. 11 in the Army and 3 in the Navy.

Cardioresponsivity testing and the collection of follow-up information are scheduled to begin around mid-October, as subjects reach week 24-26 of their pregnancies; 14 follow-up visits have already been scheduled for the month of October. Data entry is on-going as questionnaire data is collected.

CONCLUSION

Subject recruitment and data collection are proceeding as planned and in accordance with the Statement of Work. Thus, 71 women have been enrolled in the study to date, and the completeness of information obtained through interviewer-administered questionnaire is high.

Since the guidelines of the American College of Obstetrics and Gynecologists on work in pregnancy are out of date, and the U.S. government has no national regulations on hours of work, job tasks or duration of work during pregnancy, employers themselves must formulate such policies -- ideally on the basis of scientifically sound, mechanistically based studies. To help resolve the existing uncertainties, we are focusing on individual stress responses in evaluating exposure to physical and psychological work stress as risk factors for preterm delivery. The resulting information might not only help in determining work policies but also in improving understanding of the etiology of preterm birth.

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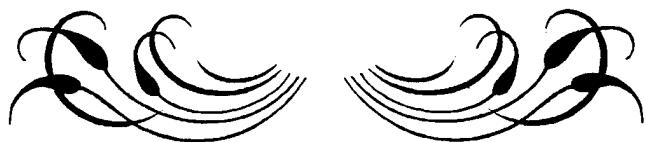
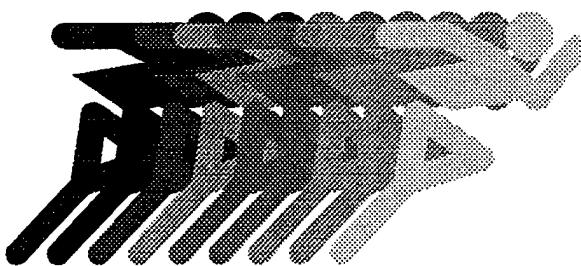
APPENDIX 1: Participant information sheet and informed consent form

WELCOME TO THE OB CLINIC

Have you ever wondered about the impact of your lifestyle and job on your pregnancy? Researchers at Mt. Sinai School of Medicine are conducting a study to explore this issue. Wilford Hall Medical Center (59th Medical Wing) is collaborating in this project and has given us permission to invite you to become a participant. We are looking for active duty pregnant women who would be willing to participate in a study of the relationship of lifestyle and work on pregnancy outcome. Participation would involve two interviews and a brief session where your response to computerized stressors is monitored.

Your participation in the study is entirely voluntary and would be kept confidential. All information used for the analysis will be based on grouped data, not on individuals. Your name will not be used. Only key study personnel directly involved with the project will have access to the master list of names and code numbers. The nurse researchers, Terri Dossey and Nora Ervin, will contact you at your new OB physical appointment.

**FOR QUESTIONS CALL 292-2023
PAGER 205-2488**



SGO #

INFORMED CONSENT DOCUMENT

**Cardiovascular Responsivity, Physical and Psychosocial Job Stress, and
the Risk of Preterm Delivery**

96HU231

1. **PURPOSE AND DURATION OF THE STUDY:** I hereby volunteer to participate as a test subject in this experimental study. The purpose of this study is to determine how active duty working conditions and job stress affect the risk of preterm delivery in military women. This study is particularly interested in women's cardiovascular reactions to various work factors and the ability of those reactions to predict preterm delivery. I qualify for participation in the research because I am pregnant and on active duty. This study will enroll 1000 active duty women over 2 1/2 years at Wilford Hall Medical Center (WHMC) and will require that I attend the obstetric clinic.

2. **PROCEDURES:** As a participant, I understand that I will be interviewed at 12-14 weeks of pregnancy about personal characteristics like age, marital status, height and weight, obstetrical, gynecological and medical history, substance abuse, various sources of stress, social support systems, and occupational and leisure time physical activity. This interview will take approximately 30 to 40 minutes. I understand that at about 25 weeks of pregnancy I will take a brief computer-controlled cognitive test involving arithmetic and word tasks, at which time my heart rate and blood pressure will be recorded. I understand that the investigators will consult my records to obtain data on past fitness assessments and on the course and outcome of my pregnancy. I understand that I will be asked to wear a small electronic device, the Caltrac, that can be attached to a belt and will keep a running count of my movements. I understand that I will be instructed in its use and that after entering my weight, height, age, and gender into the Caltrac, I will wear the device for three days placing it on a bedside table when I sleep. I understand that I will not be reimbursed for the time involved in being in this study. I understand that I will be followed throughout my pregnancy and the six week convalescent period by the WHMC obstetric service under the supervision of a staff obstetrician.

3. **RISKS OR DISCOMFORTS:** There are no foreseeable risks from participating in this research. While I might experience some psychological stress during the cognitive test, there will be no long lasting effects. I understand that the information I provide in the course of this study will be kept strictly confidential and will be used solely for research.

4. **BENEFITS:** I understand that no personal benefit is anticipated, but I will be contributing to medical science.

PATIENT COPY

Give to Patient Immediately After All Signatures/Dates Obtained

Initials _____

5. ALTERNATIVE TREATMENT: I understand that this study does not involve medical treatment of any kind, and my alternative to participating is simply to decline participation.

6. RECORDS OF STUDY PARTICIPATION: Records of my participation in this study may only be disclosed in accordance with federal law, including the Federal Privacy Act, 5 U.S.C. 552a, and implementing regulations. DD Form 2005, Privacy Act Statement - Health Care Records, contains the Privacy Act Statement for the records. I understand that records of this study may be inspected by the U.S. Food and Drug Administration (FDA) or by representatives of the U.S. Medical Research and Material Command as part of their responsibility to protect human subjects in research.

All data and medical information obtained about me as an individual will be considered privileged and held in confidence; I will not be identified in any presentation of the results. Complete confidentiality cannot be promised, particularly to subjects who are military personnel, because information bearing on my health may be required to be reported to appropriate medical or command authorities.

7. ENTITLEMENT TO CARE: I am authorized all necessary medical care for injury or disease which is the proximate result of my participation in this research. The U.S. Army requires that this institution provide such medical care when conducting research with private citizens. Other than medical care that may be provided, I will not receive any compensation for my participation in this research study; however, I understand that this is not a waiver or release of my legal rights. If I have questions about my rights or if I believe I have received a research-related injury, I may contact the Wilford Hall Medical Center Patient Representative, (210) 670-6688, and/or Dr. Barth, (210) 670-6100.

8. MEDICAL MISADVENTURE: I understand that any clinical or medical misadventure will immediately be brought to my attention or, if I am not competent at the time to understand the nature of the misadventure, such information will then be brought to the attention of my guardian or next of kin.

9. VOLUNTARY PARTICIPATION: The decision to participate in this study is completely voluntary on my part. No one has coerced or intimidated me into participating in this program. I am participating because I want to.

Teresa Dossey has accurately answered any and all questions I have about this study, my participation, and the procedures involved. I understand that Dr. Barth will be available to answer any questions concerning procedures throughout this study. I understand that if significant new findings develop during the course of this study which may relate to my decision to continue participation, I will be informed. I further understand that I may withdraw this consent at any time and discontinue further participation in this study without prejudice to my entitlements

Initials _____

to care. Should I choose to withdraw, I will continue to be treated in accordance with acceptable standards of medical treatment. I also understand that the investigator of this study may terminate my participation in this study at any time if he/she feels this to be in my best interests.

10. A copy of this form has been given to me.

VOLUNTEER'S NAME (Type or Printed) _____ PERMANENT ADDRESS _____

VOLUNTEER'S SIGNATURE _____ Volunteer's SSAN _____ Sponsor's SSAN _____ Date _____

FATHER'S NAME (Type or Printed) _____ PERMANENT ADDRESS _____

FATHER'S SIGNATURE _____ Father's SSAN _____ Date _____

Teresa J. Dossey, RN
ADVISING PHYSICIAN'S NAME (Type or Printed)

Teresa J. Dossey _____ 517-66-6497 _____
ADVISING PHYSICIAN'S SIGNATURE SSAN DATE

Nora M. ERVIN RN
WITNESS' NAME (Type or Printed)

Nora M. Ervin _____ 116-44-9889 _____
WITNESS' SIGNATURE SSAN DATE
(Must witness ALL signatures above)

TITLE OF STUDY: Cardiovascular responsivity, physical and psychosocial job stress and the risk of preterm delivery

SGO#

Date Protocol Approved by WHMC IRB: 12 Sep 96
96HU231

Date Revised ICD Approved: 27 Aug 96

Patient's Stamp Plate or Printed Name and SSAN _____

ID #

PRIVACY ACT OF 1974 APPLIES.

DD FORM 2005 FILED IN CLINICAL/MEDICAL RECORDS.

Initials _____

APPENDIX 2: Data collection forms

STUDY ID # _____
OTHER 4-DIGIT IDENTIFIER _____

**STUDY: CARDIOVASCULAR RESPONSIVITY, PHYSICAL AND PSYCHOSOCIAL
JOB STRESS, AND TIMELY DELIVERY**

PART 1. CONFIDENTIAL INFORMATION

1. Name of subject _____

Last

First

Middle

2. Social security number _____

3. Current residence _____

4. Home telephone _____

Work telephone _____

This face sheet must be separated from following pages

to protect confidentiality of subject

PART 2. CONFIDENTIAL INTERVIEW - VISIT 1

1. Date of interview _____ / _____ / _____

Time _____

2. Interviewer _____

Let me start by asking you some questions about your background.

3. What is your date of birth? _____ / _____ / _____

[Interviewer to calculate age] _____

4. Which of these groups best describes you? _____

1 = White

2 = Black

3 = Asian

4 = Hispanic

5 = Native American (Indian)

6 = Other (please specify) _____

5. Which of the following best describes your marital status? _____

1 = legally married

2 = common law married / living as married

3 = single, never married

4 = separated/divorced

5 = widowed

6. What is your height? _____ ft _____ in

7. What was your usual weight before this pregnancy? _____ lb

8. How many years of schooling have you completed? _____

Now I'd like to ask you some questions about your work.

9. What branch of the military are you in? _____

1 = army

2 = air force

3 = navy

4 = marines

10. What is your rank? _____

11. What is your current occupation? _____

12. What is your armed forces specialty code? _____

13. Have your job responsibilities changed since you became pregnant? _____

1 = no

2 = yes

If YES,

How have they changed and why? _____

Are you satisfied with those changes? _____

1 = yes

2 = no, too many changes

3 = no, too few changes

Please indicate whether the following statements about your job are true or false.

14. My job requires that I learn new things. _____

15. My job involves a lot of repetitive work. _____

16. My job requires me to be creative. _____

17. My job requires a high level of skill. _____

18. I get to do a variety of different things on my job. _____

19. I have an opportunity to develop my own special abilities. _____

Now I would like to talk a little about your social relationships. I want you to consider your supervisor, coworkers, friends, relatives and acquaintances as well as your husband/boyfriend/partner(s).

20. During the past year, was there someone with whom you could share your most private feelings (confide in)? _____

1 = yes

2 = no

What is this person's relationship to you? _____

Is there anyone else? _____ Relationship? _____

Relationship? _____

Relationship? _____

21. Is there anyone you can talk to specifically about issues at work? _____

1 = yes

2 = no

What is this person's relationship to you? _____

Is there anyone else? Relationship? _____

Relationship? _____

Relationship? _____

We're also interested in the kinds of activities you do at home.

22. With respect to housework in your household, are you: _____

1 = fully responsible?

2 = partly responsible?

3 = not at all responsible?

23. With respect to housework in your household, how satisfied are you with your partner's contribution? _____

1 = very satisfied

2 = partially satisfied

3 = not at all satisfied

4 = not applicable

24. Thinking of an average week since you became pregnant, about how many hours per week do you usually spend doing heavy housework, such as vacuuming, washing or waxing floors or cleaning the bathrooms? _____

25. Thinking of an average week since you became pregnant, how many hours per week do you usually spend in quiet leisure activities like watching television or a movie, napping, knitting, listening to music or reading? _____

26. Thinking of an average week since you became pregnant, how often does your housework involve the following activities:

1 = **very often**

2 = **fairly often**

3 = **sometimes**

4 = **almost never**

5 = **never**

climbing or balancing _____

lifting, carrying, pulling or pushing objects _____

moving around a lot _____

exerting a lot of physical effort _____

sitting or standing in uncomfortable positions for long periods of time _____

Next, I would like to ask you some questions about your reproductive history.

27. How old were you when you first started having menstrual periods? _____

28. Are you certain about this age or is it an approximation? _____

1 = certain

2 = approximate

If approximate, do you remember what grade you were in school? _____

29. The time between the first day of one period and the first day of the next period is called a cycle. During the year prior to this pregnancy, how many days on average did your cycles last? _____

30. Did you ever try to become pregnant for a year or more without success? _____

1 = no

2 = yes

31. Have you ever visited a doctor, clinic or hospital because of a problem becoming pregnant? _____

1 = no

2 = yes

32. Did the doctor give you medication to help you get pregnant? _____

1 = no

2 = yes

33. What was the name of the medication? _____

34. Did you take the medication before this pregnancy? _____

1 = no

2 = yes

Next, I would like to ask you about your previous pregnancies.

35. What was your age at your first pregnancy? _____

(If THIS is the first pregnancy, age should be the same as #3)

36. At what date (termination or delivery) did your most recent previous pregnancy end? _____ / _____ / _____

37. What was your total number of pregnancies (including all outcomes such as miscarriage, induced abortion, ectopic pregnancy) before the current one? _____

If none, go to #41

If one or more,

(a) How many of those pregnancies ended in livebirths? _____

(b) How many of those were singleton livebirths? _____

For the following three questions (38-40), please think about only your singleton livebirths (do not include pregnancies which ended in multiple births).

38. Have you had a diagnosis of pregnancy-induced hypertension in any previous pregnancy? _____

1 = no

2 = yes

If yes, during how many pregnancies? _____

39. Have you ever had a preterm birth, that is, a delivery at least three weeks prior to your due date? _____

1 = no

2 = yes

If yes, was the baby born very early (<32 weeks) or later but still preterm (33-37 weeks)? _____

40. Were any of your liveborns low birth weight? _____

1 = no

2 = yes

If yes, how many? _____

Now I would like to ask you some questions about your present pregnancy.

41. What was the first day of your last normal menstrual period? _____ / _____ / _____

42. What did the doctor say was your due date? _____ / _____ / _____

43. Were you trying to become pregnant? _____

1 = no

2 = yes

44. When you found out that you were pregnant with this pregnancy, how did you feel? _____

1 = happy you were pregnant

2 = not happy but you accepted it

3 = Other (please specify _____)

45. How about the baby's father? When he found out you were pregnant, how do you think he felt?

1 = happy you were pregnant
2 = not happy but he accepted it
3 = Other (please specify _____)

46. Prior to this pregnancy, do you have a history of infection with any of the following:

1 = no

2 = yes

Cytomegalovirus? _____

Human immunodeficiency virus? _____

Hepatitis B? _____

Toxoplasmosis? _____

Parvovirus? _____

Group B streptococcus? _____

Other (please specify _____)

47. During the first 3 months of this pregnancy, did you participate in any physical activities or exercises on a regular basis - that is, for at least 1 hour per week?

To help you, here is a list of physical activities that some women participate in.

1 = no (go to #48)

2 = yes

If YES, what kinds of activities did you take part in and how many hours per week did you spend on them?

Activity	Hours per week	Degree of exertion (0=low, 1=medium, 2=high)
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

48. Prior to this pregnancy, did you participate in any physical activity or exercise on a regular basis—that is, for at least 1 hour per week during the previous 3 months? Here are examples of some physical activities.

1 = no (go to #49)

2 = yes

If YES, what kinds of activities did you take part in and how many hours per week did you spend on them?

Activity	Hours per week	Degree of exertion (0=low, 1=medium, 2=high)

I would also like to ask about some methods you may have used to maintain feminine hygiene.

49. Have you ever douched - washed out the vagina using solution from a bag/bottle?

1 = no (go to NIOSH QUESTIONNAIRE)

2 = yes

50. Prior to this pregnancy, how often did you douche?

1 = regularly, at least once a week

2 = at least once a month

3 = not regularly, but more than 5 times a year

4 = occasionally, but less than 5 times a year

5 = rarely

51. What type of solution did you usually use for douching?

1 = over-the-counter product (specify _____)

2 = homemade water and vinegar

3 = water only

4 = other (specify) _____

52. Have you douched during the current pregnancy?

1 = no

2 = yes

GO TO NIOSH QUESTIONNAIRE

PART 3. CONFIDENTIAL INTERVIEW - VISIT 2

1. Date of interview ____ / ____ / ____

Time _____

Interviewer _____

Let me start by asking you some questions about childcare.

2. How many children in your household are under the age of 6 years?
(If none, go to #5) _____

3. Do you use a baby-sitter (including friend, family member or paid sitter) or day-care facility for them?

1 = no
2 = yes

4. Are you satisfied with the care provided for your child(ren)?

1 = no
2 = yes

5. Have you made arrangements for daycare for the child of this pregnancy?

1 = no (go to #6)
2 = yes

If YES,

What specific arrangements have you made? _____

Are you satisfied with those arrangements?

1 = no
2 = yes

6. Do you have concerns about day care for the child of this pregnancy?

1 = no
2 = yes

If YES, what are your specific concerns? _____

Now I'd like to ask you some questions about your work.

7. Have your job responsibilities changed since our previous interview?

1 = no (go to #14)
2 = yes

If YES,

How have they changed? _____

Why were these changes made? _____

Are you satisfied with these changes?

- 1 = yes
- 2 = no, too many changes
- 3 = no, too few changes

Please indicate whether the following statements about your job are true or false.

- 8. My job requires that I learn new things. _____
- 9. My job involves a lot of repetitive work. _____
- 10. My job requires me to be creative. _____
- 11. My job requires a high level of skill. _____
- 12. I get to do a variety of different things on my job. _____
- 13. I have an opportunity to develop my own special abilities. _____

Let me ask about the kinds of activities you have been doing at home during your pregnancy.

- 14. Thinking of an average week during your second trimester, about how many hours per week do you usually spend doing heavy housework, such as vacuuming, washing or waxing floors or cleaning the bathrooms? _____
- 15. Thinking of an average week during your second trimester, how many hours per week do you usually spend in quiet leisure activities like watching television or a movie, napping, knitting, listening to music or reading? _____

STUDY ID # _____
OTHER 4-DIGIT IDENTIFIER _____

16. Thinking of an average week during your second trimester, how often does your housework involve the following activities:

1 = very often
2 = fairly often
3 = sometimes
4 = almost never
5 = never

climbing or balancing _____

lifting, carrying, pulling or pushing objects _____

moving around a lot _____

exerting a lot of physical effort _____

sitting or standing in uncomfortable positions for long periods of time _____

Now I would like to ask you some questions about your present pregnancy.

17. Have you been douching during your second trimester?

1 = no
2 = more than once a week
3 = once a week
4 = 1 - 3 times a month
5 = less than once a month

18. Have you ever smoked at least once a day for a period of three months or longer?

1 = no (go to #19)
2 = yes

If YES, at what age did you begin smoking? _____

Have you smoked during this pregnancy? _____

1 = no **2 = yes, but have stopped**

How many weeks ago did you stop? _____

What was your usual number of cigarettes
per WORK-day? _____

per NON-WORK day? _____

3 = yes, still smoking

What is your usual number of cigarettes
per WORK-day? _____

per NON-WORK day? _____

STUDY ID # _____
OTHER 4-DIGIT IDENTIFIER _____

19. Does any other member of your household or workplace smoke in your presence?

1 = no

2 = yes

If YES, about how many hours per week on average? _____

20. Does the father of the baby smoke?

1 = no

2 = yes

21. Do you ever drink coffee?

1 = no (go to #22)

2 = yes

If YES, have you been drinking coffee during this pregnancy? _____

1 = no 2 = yes, but have stopped.

How many weeks ago did you stop? _____

What was your usual number of ounces (# cups X ounces drank per cup -- please compensate for unfinished cups, cans, bottles)

per WORK-day? _____

per NON-WORK day? _____

1 = Regular or 2 = decaf? _____

3 = yes, but only occasionally (<1 cup per day) _____

4 = yes, still drinking coffee

What is your usual number of ounces (# cups X ounces drank per cup -- please compensate for unfinished cups, cans, bottles)

per WORK-day? _____

per NON-WORK day? _____

1 = Regular or 2 = decaf? _____

22. Do you ever drink caffeinated sodas, tea or iced tea?

1 = no (go to #23)

2 = yes

If YES, have you been drinking them during this pregnancy? _____

1 = no 2 = yes, but have stopped.

How many weeks ago did you stop? _____

What was your usual number of ounces (# cups X ounces drank per cup -- please compensate for unfinished cups, cans, bottles)

per WORK-day? _____

per NON-WORK day? _____

1 = Regular or 2 = diet? _____

3 = yes, but only occasionally (<1 can/cup per day)

4 = yes, still drinking soda/tea

What is your usual number of ounces (# cups X ounces drank per cup -- please compensate for unfinished cups, cans, bottles)

per WORK day? _____

per day? _____

1 = Regular or 2 = diet? _____

23. Have you been drinking alcohol (any type) during this pregnancy? _____

1 = never

2 = occasionally (one or fewer glasses/bottles/drinks per month on average)

3 = more than occasionally

If more than occasionally, number of "shot equivalents" (1 shot hard liquor straight or mixed = 12 oz. beer = 4 oz. wine) per:

month _____, week _____, or day _____

24. Did you take any of the following medications at least once during your pregnancy?

If YES, during what month of this pregnancy did you first/last take this?

<i>Medicine</i>	<i>Specify</i>	<i>First month</i>	<i>Last month</i>
-----------------	----------------	--------------------	-------------------

Analgesic _____

Antibiotic _____

Antidepressant _____

STUDY ID # _____
OTHER 4-DIGIT IDENTIFIER _____

Antacid	_____	_____	_____
Asthma medicine	_____	_____	_____
Blood pressure medicine	_____	_____	_____
Cough medicine	_____	_____	_____
Diet pills	_____	_____	_____
Diuretic	_____	_____	_____
Female hormones	_____	_____	_____
Insulin	_____	_____	_____
Nasal spray	_____	_____	_____
Pills to stay awake	_____	_____	_____
Seizure medicine	_____	_____	_____
Thyroid medicine	_____	_____	_____
Tocolytic drugs	_____	_____	_____
Other	_____	_____	_____

25. Have you had bleeding or spotting during this pregnancy? _____
1 = no (go to #31)
2 = yes

26. If YES, how many different times did you have bleeding or spotting? _____

27. During which trimester did you have bleeding or spotting? _____
1 = first
2 = second
3 = both

28. On average, how many days did each episode last? _____

29. At its worst, did you have:
1 = spotting
2 = slight bleeding
3 = moderate bleeding
4 = heavy bleeding

30. Did a doctor give you a reason or diagnosis for the bleeding? _____
1 = no
2 = Placenta previa
3 = Placenta abruptio
4 = Cervicitis
5 = Threatened miscarriage
6 = Other (please specify _____)

31. Did you experience nausea and/or vomiting during this pregnancy? _____
1 = no (go to #35)
2 = yes

32. During which trimester did you experience nausea and/or vomiting? _____

33. On average, how many days did each episode last? _____

34. In general, would you describe it as:
1 = mild to moderate
2 = required IV hydration
3 = required hospitalization

35. Have you experienced or been diagnosed with any of the following conditions during this pregnancy:
1 = no
2 = yes

Bacterial infection (ear, kidney, bladder)? _____

Diabetes? _____

High blood pressure? _____

Injury or accident? _____

Mumps, rubella, measles, chicken pox? _____

Upper respiratory infection (cold, cough, sore throat)? _____

Influenza (flu)? _____

Asthma? _____

Vaginal herpes blisters? _____

Rh blood problems? _____

STUDY ID # _____
OTHER 4-DIGIT IDENTIFIER _____

36. During the second 3 months of this pregnancy, did you participate in any physical activities or exercises on a regular basis - that is, for at least 1 hour per week? To help you, here is a list of physical activities that some women participate in.

1 = no

2 = yes

If YES, what kinds of activities did you take part in and how many hours per week did you spend on them?

<i>Activity</i>	<i>Hours per week</i>	<i>Degree of exertion</i> (0=low, 1=medium, 2=high)

GO TO NIOSH QUESTIONNAIRE

NIOSH QUESTIONNAIRE

Now I'd like to ask you more about your work life *General job information*

1. Which of the following best describes your present work shift? _____
1 = permanent day shift
2 = permanent evening shift
3 = permanent night shift
4 = rotating eight-hour shift
5 = rotating twelve-hour shift
6 = other (specify _____)

2. How long have you worked this shift? _____ years _____ months

3. How many times a week do you change shifts? _____
1 = I don't change
2 = 1-2 times
3 = more than 2 times
4 = on call
5 = standby
6 = non-standard work week
7 = other (specify _____)

4. How many hours do you normally work per week? _____

5. Thinking of an average week since you became pregnant,
 - a) how often does your job involve the following activities:
1 = **never**
2 = **occasionally**
3 = **sometimes**
4 = **fairly often**
5 = **very often**

climbing or balancing _____
lifting, carrying, pulling or pushing _____
moving around a lot _____
exerting a lot of physical effort _____

 - b) how many hours of uninterrupted standing does your job require? _____

Physical environment

Please indicate whether the following statements about your job are true or false. You may find it difficult to choose one or the other response. Just do your best and select the answer that describes the situation most accurately.

1 = True

2 = False

6. The level of noise in the area(s) in which I work is usually high. _____
7. The level of lighting in the area(s) in which I work is usually poor. _____
8. The temperature of my work area(s) during the summer is usually comfortable. _____
9. The temperature of my work area(s) during the winter is usually comfortable. _____
10. The humidity in my work area(s) is usually uncomfortable. _____
11. The level of air circulation in my work area(s) is good. _____
12. The air in my work area(s) is clean and free of pollution. _____
13. In my job, I am well protected from exposure to dangerous substances. _____
14. The overall quality of the physical environment where I work is poor. _____
15. My work area(s) is/are awfully crowded. _____

Work hazards

16. How often does your job expose you to verbal abuse and/or confrontations with supervisors or coworkers? _____

1 = never

2 = occasionally

3 = sometimes

4 = fairly often

5 = very often

17. How often does your job expose you to the threat of physical harm or injury? _____

1 = never

2 = occasionally

3 = sometimes

4 = fairly often

5 = very often

18. How often have you been physically assaulted within the past 12 months while performing your job? _____

1 = never
2 = occasionally
3 = sometimes
4 = fairly often
5 = very often

Your job (Role conflict/ambiguity)

How accurate are each of the following statements in describing your job? Use the following response categories to represent the degree of accuracy:

1 = very inaccurate
2 = mostly inaccurate
3 = slightly inaccurate
4 = uncertain
5 = slightly accurate
6 = mostly accurate
7 = very accurate

19. I feel certain about how much authority I have. _____

20. There are clear, planned goals and objectives for my job. _____

21. I have to do things that should be done differently. _____

22. I know that I have divided my time properly between various tasks. _____

23. I receive an assignment without the help I need to complete it. _____

24. I know what my responsibilities are. _____

25. I have to bend or break a rule or policy in order to carry out an assignment. _____

26. I work with two or more groups who operate quite differently. _____

27. I know exactly what is expected of me. _____

28. I receive conflicting requests from two or more people. _____

29. I do things that are likely to be accepted by one person and not accepted by others. _____

30. I receive an assignment without adequate resources and materials to execute it. _____

31. Explanation is clear about what has to be done on my job. _____

32. I work on unnecessary things. _____

Control scale

The next series of questions asks how much influence you now have in each of several areas. By influence we mean the degree to which you control what is done by others at work and have freedom to determine what you do yourself at work.

Use the following response categories:

- 1 = very little
- 2 = little
- 3 = a moderate amount
- 4 = much
- 5 = very much

33. How much influence do you have over the variety of tasks you perform? _____

34. How much influence do you have over the availability of supplies and equipment you need to do your work? _____

35. How much influence do you have over the order in which you perform tasks at work? _____

36. How much influence do you have over the amount of work you do? _____

37. How much influence do you have over the pace of your work, that is how fast or slow you work? _____

38. How much influence do you have over the quality of the work you do? _____

39. How much influence do you have over the arrangement and decoration of your work area? _____

40. How much influence do you have over the decisions concerning which individuals in your work unit do which tasks? _____

41. How much influence do you have over the hours or schedule that you work? _____

42. How much influence do you have over the decisions as to when things will be done in your work unit? _____

43. How much do you influence the policies, procedures, and performance in your unit? _____

44. How much influence do you have over the training of other workers in your unit? _____

45. How much influence do you have over the arrangement of furniture and _____

other work equipment in your work area? _____

46. To what extent can you do your work ahead and take a short rest break during work hours? _____

47. In general, how much influence do you have over work and work-related factors? _____

Job requirements

Now I would like you to indicate how often certain things happen at your job. Please base your responses on the following scale:

1 = rarely
2 = occasionally
3 = sometimes
4 = fairly often
5 = very often

48. How often does your job require you to work very fast? _____

49. How often does your job require you to work very hard? _____

50. How often does your job leave you with little time to get things done? _____

51. How often is there a great deal to be done? _____

52. How often is there a marked increase in the work load? _____

53. How often is there a marked increase in the amount of concentration required on your job? _____

54. How often is there a marked increase in how fast you have to think? _____

55. How often does your job let you use the skills and knowledge you learned in school? _____

56. How often are you given a chance to do the things you do best? _____

57. How often can you use the skills from your previous experience and training? _____

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Workload and responsibility

The next few items are concerned with various aspects of your work activities. Please indicate how much of each you have on your job by using the following scale:

- 1 = hardly any
- 2 = a little
- 3 = some
- 4 = a lot
- 5 = a great deal

58. How much slowdown in the work load do you experience? _____

59. How much time do you have to think and contemplate? _____

60. How much work load do you have? _____

61. What quantity of work do others expect you to do? _____

62. How much time do you have to do all your work? _____

63. How many projects, assignments or tasks do you have? _____

64. How many lulls between heavy work load periods do you have? _____

65. How much responsibility do you have for the future of others? _____

66. How much responsibility do you have for the job security of others? _____

67. How much responsibility do you have for the morale of others? _____

68. How much responsibility do you have for the welfare and lives of others? _____

Mental demands

Please indicate the degree to which you agree or disagree with the following statements about your job. Use the following scale:

- 1 = strongly agree
- 2 = slightly agree
- 3 = slightly disagree
- 4 = strongly disagree

69. My job requires a great deal of concentration. _____

70. My job requires me to remember many different things. _____

71. I must keep my mind on my work at all times. _____

72. I can take it easy and still get my work done. _____

73. I can let my mind wander and still do the work. _____

Job satisfaction

I would like you to think about the type of work you do in your job. In answering, please focus on your current job, not on the military overall.

74. Knowing what you know now, if you had to decide all over again whether to take the type of job you now have, what would you decide? _____

1 = I would decide without hesitation to take the same job
2 = I would have some second thoughts
3 = I would decide definitely not to take this type of job

75. If you were free right now to go into any type of job you wanted, what would your choice be? _____

1 = I would take the same job
2 = I would take a different job
3 = I would not want to work

76. If a friend of yours told you they were interested in working in a job like yours, what would you tell them? _____

1 = I would strongly recommend it
2 = I would have doubts about recommending it
3 = I would advise against it

77. All in all, how satisfied would you say you are with your job? _____

1 = very satisfied
2 = somewhat satisfied
3 = not too satisfied
4 = not at all satisfied

Problems at work

People deal with day to day problems at work in many ways. When faced with problems at work, how often do you do each of the following? Please use this scale:

1 = rarely
2 = occasionally
3 = sometimes
4 = fairly often
5 = very often

78. Make a plan to solve the problem(s) and stick to it. _____

79. Go on as if nothing has happened. _____

80. Feel responsible for the problem(s). _____

81. Daydream or wish that you could change the problem(s). _____

82. Talk to your boss or co-workers about the problem(s). _____

83. Become more involved in activities outside of work. _____

Social support

84. How much does each of these people go out of their way to do things to make your work life easier for you?

1 = don't have any such person

2 = not at all

3 = a little

4 = somewhat

5 = very much

your immediate supervisor (boss) _____

other people at work _____

your spouse/partner _____

your relatives _____

your friends _____

85. How easy is it to talk with each of the following people?

1 = don't have any such person

2 = not at all

3 = a little

4 = somewhat

5 = very easy

your immediate supervisor (boss) _____

other people at work _____

your spouse/partner _____

your relatives _____

your friends _____

86. How much can each of these people be relied on when things get tough at work?

- 1 = don't have any such person
- 2 = not at all
- 3 = a little
- 4 = somewhat
- 5 = very much

your immediate supervisor (boss) _____

other people at work _____

your spouse/partner _____

your relatives _____

your friends _____

87. How much is each of the following willing to listen to your personal problems?

- 1 = don't have any such person
- 2 = not at all
- 3 = a little
- 4 = somewhat
- 5 = very much

your immediate supervisor (boss) _____

other people at work _____

your spouse/partner _____

your relatives _____

your friends _____

Thank you. You have been very helpful. We appreciate your contribution to our study, which we hope will help us understand what factors lead to a healthy pregnancy.

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Perceived Stress Scale

The questions in this scale ask you about your feelings and thoughts during the last month. In each case, you will be asked to indicate *how often* you felt or thought a certain way. Although some of the questions are similar, there are differences between them and you should treat each one as a separate question. The best approach is to answer each question fairly quickly. That is, don't try to count up the number of times you felt a particular way, but rather indicate the alternative that seems like a reasonable estimate.

For each question, choose from the following alternatives:

0. never
1. almost never
2. sometimes
3. fairly often
4. very often

STUDY ID # _____
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1. In the last month, how often have you been upset because of something that happened unexpectedly? _____
2. In the last month, how often have you felt that you were unable to control the important things in your life? _____
3. In the last month, how often have you felt nervous and “stressed”? _____
4. In the last month, how often have you dealt successfully with irritating life hassles? _____
5. In the last month, how often have you felt that you were effectively coping with important changes that were occurring in your life? _____
6. In the last month, how often have you felt confident about your ability to handle your personal problems? _____
7. In the last month, how often have you felt that things were going your way? _____
8. In the last month, how often have you found that you could not cope with all the things that you had to do? _____
9. In the last month, how often have you been able to control irritations in your life? _____
10. In the last month, how often have you felt that you were on top of things? _____
11. In the last month, how often have you been angered because of things that happened that were outside of your control? _____
12. In the last month, how often have you found yourself thinking about things that you have to accomplish? _____
13. In the last month, how often have you been able to control the way you spend your time? _____
14. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them? _____

STUDY ID # _____
 OTHER 4-DIGIT IDENTIFIER _____
 DATE ____/____/____

General Health Questionnaire (12-Item Version)

We should like to know if you have had any medical complaints, and how your health has been in general, *over the past few weeks*. Please answer ALL the questions on the following page simply by underlining the answer which you think most nearly applies to you. Remember that we want to know about present and recent complaints, not those that you had in the past. It is important that you try to answer ALL the questions.

HAVE YOU RECENTLY:				
	Better than usual	Same as usual	Less than usual	Much less than usual
1. been able to concentrate on whatever you're doing?				
2. lost much sleep over worry?				
3. felt that you are playing a useful part in things?				
4. felt capable of making decisions about things?				
5. felt constantly under strain?				
6. felt you couldn't overcome your difficulties?				
7. been able to enjoy your normal day-to-day activities?				
8. been able to face up to your problems?				
9. been feeling unhappy and depressed?				
10. been losing confidence in yourself?				
11. been thinking of yourself as a worthless person?				
12. been feeling reasonably happy, all things considered?				

STUDY ID # _____
OTHER 4-DIGIT IDENTIFIER _____
DATE _____ / _____ / _____

In this questionnaire are groups of statements. Please read each group of statements carefully. Then pick the one statement in each group which best describes the way you have been feeling the PAST WEEK, INCLUDING TODAY! Circle the number beside the statement you picked. If several statements in the group seem to apply equally well, circle each one. Be sure to read all the statements in each group before making your choice.

- 1 0 I do not feel sad.
 1 I feel sad.
 2 I am sad all the time and can't snap out of it.
 3 I am so sad or unhappy that I can't stand it.

- 2 0 I am not particularly discouraged about the future.
 1 I feel discouraged about the future.
 2 I feel I have nothing to look forward to.
 3 I feel that the future is hopeless and that things cannot improve.

- 3 0 I do not feel like a failure.
 1 I feel I have failed more than the average person.
 2 As I look back on my life, all I can see is a lot of failures.
 3 I feel I am a complete failure as a person.

- 4 0 I get as much satisfaction out of things as I used to.
 1 I don't enjoy things the way I used to.
 2 I don't get real satisfaction out of anything anymore.
 3 I am dissatisfied or bored with everithing.

- 5 0 I don't feel particularly guilty.
 1 I feel guilty a good part of the time.
 2 I feel quite guilty most of the time.
 3 I feel guilty all of the time.

- 6 0 I don't feel I am punished.
 1 I feel I may be punished.
 2 I expect to be punished.
 3 I feel I am being punished.

- 7 0 I don't feel disappointed in myself.
 1 I am disappointed in myself.
 2 I am disgusted with myself.
 3 I hate myself.

- 8 0 I don't feel I am worse than anybody else.
 1 I am critical of myself for my weakness or mistakes.
 2 I blame myself all the time for my faults.
 3 I blame myself for everything bad that happens.

- 9 0 I don't have any thoughts of killing myself.
 1 I have thoughts of killing myself, but I would not carry them out.
 2 I would like to kill myself.
 3 I would kill myself if I had the chance.

- 10 0 I don't cry any more than usual.
 1 I cry more now than I used to.
 2 I cry all the time now.
 3 I used to be able to cry, but now I can't cry even though I want to.

STUDY ID # _____
OTHER 4-DIGIT IDENTIFIER _____

DATE ____/____/____

11 0 I am no more irritated now than I ever am.
1 I get annoyed or irritated more easily than I used to.
2 I feel irritated all the time now.
3 I don't get irritated at all by the things that used to irritate me.

12 0 I have not lost interest in other people.
1 I am less interested in other people than I used to be.
2 I have lost most of my interest in other people.
3 I have lost all of my interest in other people.

13 0 I make decisions about as well as I ever could.
1 I put off making decisions more than I used to.
2 I have greater difficulty in making decisions than before.
3 I can't make decisions at all anymore.

14 0 I don't feel I look any worse than I used to.
1 I am worried that I am looking old or unattractive.
2 I feel that there are permanent changes in my appearance that make me look unattractive.
3 I believe that I look ugly.

15 0 I can work about as well as usual.
1 It takes an extra effort to get started at doing something.
2 I have to push myself very hard to do anything.
3 I can't do any work at all.

16 0 I can sleep as well as before.
1 I don't sleep as well as I used to.
2 I wake up 1-2 hours earlier than usual and find it hard to get back to sleep.
3 I wake up several hours earlier than I used to and cannot get back to sleep.

17 0 I don't get more tired than usual.
1 I get tired more easily than I used to.
2 I get tired from doing almost anything.
3 I am too tired to do anything.

18 0 My appetite is no worse than usual.
1 My appetite is not as good as it used to be.
2 My appetite is much worst now.
3 I have no appetite at all anymore.

19 0 I haven't lost much weight, if any, lately.
1 I have lost more than 5 pounds.
2 I have lost more than 10 pounds.
3 I have lost more than 15 pounds.

20 I am purposely trying to lose weight by eating less.
Yes No

21 0 I am no more worried about my health than usual.
1 I am worried about physical problems such as aches and pains; or upset stomach; or constipation.
2 I am very worried about physical problems and it's hard to think of much else.
3 I am so worried about my physical problems that I cannot think about anything else.

22 0 I have not noticed any recent change in my interest in sex.
1 I am less interested in sex than I used to be.
2 I am much less interested in sex now.
3 I have lost interest in sex completely.

STUDY ID # _____
OTHER 4-DIGIT IDENTIFIER _____

PART 4. MEDICAL RECORD INFORMATION

1. Date (start of) last normal menstrual period _____ / _____ / _____

2. Has ultrasound been performed? _____

1 = no (go to #3)

2 = yes

a) Date of first ultrasound _____ / _____ / _____

b) What is the estimated date of confinement (EDC) based on the ultrasound? _____ / _____ / _____

c) What were the significant findings of the ultrasound?

(go to #4)

3. What is the physician's best estimate of the estimated date of confinement (EDC) in the absence of ultrasound? _____ / _____ / _____

4. Date at entry to prenatal care _____ / _____ / _____

5. Were any of the following procedures performed during the current pregnancy?

	Date	Abnormality
Chorionic villus sampling?	____ / ____ / ____	_____
Amniocentesis?	____ / ____ / ____	_____
AFP (spina bifida) test?	____ / ____ / ____	_____

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OTHER 4-DIGIT IDENTIFIER _____

6. Prenatal visits record

7. Past pregnancies (use separate line for each birth if history of multiple gestations)

STUDY ID # _____
OTHER 4-DIGIT IDENTIFIER _____

8. Hospitalizations during pregnancy but prior to delivery

<i>Indication for admission</i>	<i>Date</i>	<i>Duration (days)</i>
_____	____ / ____ / ____	_____
_____	____ / ____ / ____	_____
_____	____ / ____ / ____	_____
_____	____ / ____ / ____	_____

9. Job modifications during pregnancy

<i>Indication for job change</i>	<i>Date</i>	<i>Duration (days)</i>
_____	____ / ____ / ____	_____
_____	____ / ____ / ____	_____
_____	____ / ____ / ____	_____
_____	____ / ____ / ____	_____

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OTHER 4-DIGIT IDENTIFIER _____

10. Laboratory data during pregnancy

INITIAL

Blood type _____

Rh type _____

Rubella titer _____

VDRL _____

Hematocrit _____

PLT _____

Pap _____

AB screen _____

Urine culture _____

if positive, specify _____

16 WEEK

Alpha fetoprotein _____

1° GTT _____

28 WEEK

3° GTT _____

AB screen _____

34 WEEK

HCT _____

PLT _____

11. Conditions during present pregnancy

1 = no

2 = yes

vaginal/uterine bleeding? _____

vaginal discharge/odor? _____

vomiting? _____

constipation? _____

headache? _____

abdominal pain? _____

urinary complaints? _____

febrile episode? _____

other? _____

12. History of any of the following

1 = no

2 = yes

diabetes? _____

hypertension? _____

heart disease? _____

rheumatic fever? _____

mitral valve prolapse? _____

kidney disease? _____

urinary tract infection? _____

nervous and mental disorders? _____

epilepsy? _____

hepatitis? _____

liver disease? _____

varicosities? _____

phlebitis? _____

thyroid dysfunction? _____

tuberculosis? _____

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asthma? _____

GYN surgery? _____

abnormal pap? _____

uterine anomaly? _____

infertility? _____

in utero DES exposure? _____

other? _____

13. History of infection with any of the following

1 = no

2 = yes

syphilis? _____

gonorrhea? _____

herpes simplex virus (HSV)? _____

human papillomavirus (HPV)? _____

chlamydia? _____

**AT THE PREGNANCY'S TERM, THE FOLLOWING IS TO BE ASCERTAINED
FROM THE MEDICAL RECORDS:**

14. Date of admission: _____ / _____ / _____

15. Date of delivery: _____ / _____ / _____

Time _____

16. Maternal weight at time of delivery _____ lbs

17. Was labor spontaneous or induced? _____

1 = spontaneous (go to #18)

2 = induced

a) If induced, reason for induction? _____

18. Did membrane rupture spontaneously? _____

1 = no

2 = yes, date _____ / _____ / _____

time _____

19. Type of delivery: _____

1 = spontaneous

2 = assisted breech

3 = forceps

4 = vacuum

5 = cesarean

20. Indication for operative delivery: _____

1 = no

2 = yes

elective _____

failure to progress _____

abnormal presentation _____

fetal distress _____

repeat c/section _____

failed attempted VBAC _____

prematurity _____

placenta previa _____

abruptio placenta _____

prolapsed cord _____

failed forceps/extraction _____

herpes _____

amnionitis _____

multiple gestation _____

other (specify _____)

21. Was father present at delivery? _____

1 = no

2 = yes

22. Was any other family member or friend present at delivery? _____

1 = no

2 = yes, relationship _____

23. Outcome _____

1 = liveborn delivery

2 = stillborn

24. Gender of the baby _____

1 = male

2 = female

25. Gestational age (weeks) _____

26. Birth weight (grams) _____

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27. Birth length (cm) _____

28. Head circumference (cm) _____

29. Any major congenital anomaly? _____

1 = no

2 = yes

If YES, please specify: _____

30. Apgar score 1 minute _____

31. Apgar score 5 minutes _____

APPENDIX 3: Non-participant questionnaire

Study ID # _____
SSN # _____

NON-PARTICIPANT QUESTIONNAIRE

1. What is your date of birth? _____
2. Which of these groups best describes you? _____
 - 1) White
 - 2) Black
 - 3) Asian
 - 4) Hispanic
 - 5) Native American (Indian)
 - 6) Other (please specify) _____
3. Which of the following best describes your marital status? _____
 - 1) Legally married
 - 2) Common law married/living as married
 - 3) Single, never married
 - 4) Separated/Divorced
 - 5) Widowed
4. What branch of the military are you in? _____
5. What is your rank? _____
6. What is your current occupation? _____
7. What is your armed forces specialty code (AFSC) or MOS? _____
8. What was your total number of pregnancies (including all outcomes) before this current one? _____
 - a. What was the number of:
Liveborn _____ Male _____ Female _____
Preterm _____ (born at least three weeks prior to your due date)
Stillborn _____
Induced abortions _____
Miscarriages _____
Ectopic _____
Twin Pregnancies _____
9. Why did you choose not to participate in this study? _____

APPENDIX 4: Bibliography and list of personnel

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LIST OF PERSONNEL

Maureen C. Hatch, Ph.D.	Principal Investigator
Major William H. Barth, M.D.	Principal Investigator at Wilford Hall USAF Medical Center
Gertrud Berkowitz, Ph.D.	Co-Principal Investigator
Robert Lapinski, Ph.D.	Co-Investigator
Teresa Dossey, R.N.	Project Coordinator at Wilford Hall USAF Medical Center
Nora Ervin, R.N.	Assistant to the Project Coordinator at Wilford Hall USAF Medical Center
Loren Lipworth, Sc.D.	Research Assistant to Dr. Hatch and the NYC Investigators
Richard Sloan, Ph.D.	Consultant